REMARKS

Claim 42 is the only claim remaining in the case. No claims have been allowed. The official action of November 19, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method of modulating the activity of a member of the polo serine/threonine kinase family in a subject by administering an amount of a specified peptide which is effective to so modulate the activity of the kinase. The peptide is one of SEQ ID NOS: 15-19.

The examiner has acknowledged applicant's election without traverse of Group III, but states that applicant has not elected a specific peptide as also required by the restriction requirement. However, the examiner has searched and examined SEQ ID NOS: 15-19 as drawn to the elected invention Group III.

Applicant hereby confirms election of SEQ ID NOS: 15-19. The claims have now been amended to be directed only to the elected embodiment.

The examiner has objected to the specification because of certain specified spelling mistakes. While the

examiner referred to the abstract, it is apparent that the examiner intended to refer to page 2 of the specification.

The spelling errors on page 2 of specification noted by the examiner have been corrected, as have other errors noted in the specification, thus obviating this objection.

Claim 1 has been objected to as deletion of "according" has been required.

Claim 1 has now been deleted, thus obviating this objection.

Claims 1-39 and 42-50 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The examiner states that the disclosure fails to meet the enablement requirement for the use of the elected peptides in a method for modulating the activity of a serine/threonine kinase in a subject. The examiner states that the claims call for the use of peptide derivatives, that the art teaches that amino acid changes can substantially alter a peptide, that the evidence of pharmacological activity is done *in vitro*, and the claims are drawn to a broad range of peptide derivatives. This rejection is respectfully traversed.

The examiner's comments about derivatives have now been obviated by the present amendment to claim 42, which now is directed only to the use of the five specific peptides that the examiner agrees are free of the prior art. Furthermore, claim 42 now defines the therapeutic effect as being administration of an amount effective to modulate the activity of the serine/threonine kinase in the subject. Furthermore, the serine/threonine kinase has been defined as being a member of the polo serine/threonine kinase family. As indicated in Figure 4, all five of the presently claimed peptide sequences are from the polo family. This is language that had previously been used in claim 46.

The examiner recognizes that two of the five related peptides were tested for their ability to modulate serine/threonine kinase in Example 2. The examiner objects to this in stating that this does not show activity "in a subject". However, there is no requirement in any statute or rule that clinical tests must be conducted before a patent can be issued on a therapeutic process, or even that *in vivo* tests must be conducted. The *in vitro* tests of Example 2, which are conducted on living cells, bear sufficient correlation with the claimed utility to satisfy the enablement requirement. See MPEP § 2164.02. The claims are directed to modulating serine/threonine kinase activity in a subject. The tests show

modulation of serine/threonine kinase in living cells *in vitro*. The examiner has not satisfied his burden of giving reasons for a conclusion of lack of correlation. As stated in MPEP § 2164.02, a rigorous or an invariable exact correlation is not required. Accordingly, reconsideration and withdrawal of this rejection are respectfully urged.

Claims 1-39 and 42-50 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being potentially enabling for the use of six sequences in modulating serine/threonine *in vitro* but not in a subject, has not enabled any peptide sequences or derivatives for modulating serine/threonine activity in a subject. This rejection is respectfully traversed.

In view of the amendment of the claims to be directed only to the use of the five elected species, this breadth rejection does not appear to differ from the previous rejection discussed above. It is not necessary to have a working example of use in a subject in order to provide enabling support for the claims. Clearly, the specification states that the peptides may be used for modulation of serine/threonine kinase in a subject. The working example is an *in vitro* experiment on living cells. An *in vitro* experiment on living cells correlates with *in vivo* use on living cells. As discussed above, this is sufficient to

comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, insofar as the how to use requirement is concerned. Reconsideration and withdrawal of this rejection for the above reasons, as well as for the same reasons as discussed above with respect to the previous rejection, are therefore respectfully urged.

Claims 1-39 and 42-50 have been rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite in the term "therapeutically effective amount". The examiner suggests that applicant distinctly claim what "therapeutically effective amount" is used.

Claim 42 has now been amended to delete the term "therapeutically effective amount" and to substitute the phrase "an amount effective to modulate the activity of the serine/threonine kinase in the subject". It is believed that this language explains what the effective amount is, using appropriate functional terminology. Reconsideration and withdrawal of this rejection are therefore also respectfully urged.

It is noted that the examiner has stated that notwithstanding the above rejections, SEQ ID NOS: 15-19 were found to be free of the prior art.

It is submitted that all of the claims now present in this case clearly define over the references of record and fully comply with 35 U.S.C. § 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By
Roger L. Browdy
Registration No. 25,618

RLB:jab
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\K\kery\Ben-Sasson2B\Pto\AmendmentA.doc